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# **EU-Chemical Policy**

# **REACH**

**Principle, Application and Consequences**

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**Hannover, 6. Februar 2007**

**Advanced Rubber Technology (ART)  
-Metropolregion-**

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# Chemical Policy

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For the past decade, environmental protection issues have represented a major priority of the European legislators.

In January 2005, the EU Environment Commissioner, S. Dimas further emphasized this :

**“...keeping a high level of environmental protection remains at the heart of the European project.”**

Remarks:

**European Tyre Industry and General Goods Industry**

**Currently uses 4000 raw materials of which 90 % are preparations**

# Reasons for a New EU Chemical Policy

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- Existing Patchwork of Directives and Regulations
- Gaps in information about the effects of the majority of existing chemicals on health and environment
- Unsufficient identification and assessment of risks and exposure of hazard substances to humans/environment
- Distinction in testing "existing" ↔ "new" chemicals  
(cut off 1981, high requirements in testing for "new" chemicals, > 10 kg /a)
- Disadvantage in research and innovation for the European chemical industry



REACH,  
1<sup>st</sup> publication  
in 2001

# Objectives of the New Chemical Policy

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- Protection of human health and the environment
- Maintenance and enhancement of the competitiveness of EU chemical industry
- Prevention of fragmentation of the internal market
- Increase transparency
- Integration with international effort
- Promotion of non-animal testing
- Conformity with EU international obligations

# Scope of REACH



## Covered Substances:

- on their own,
- in preparations
- in articles,
- manufactured,
- used as intermediates,
- placed on the market,

## Exempted Substances:

- radioactive,
- subject to customs supervision,
- non-isolated intermediates,
- waste,
- food, (is not a substance, preparation or article)
- used in the interests of defence (decision by the member states)



**Other equivalent legislation**

# Substances in Articles

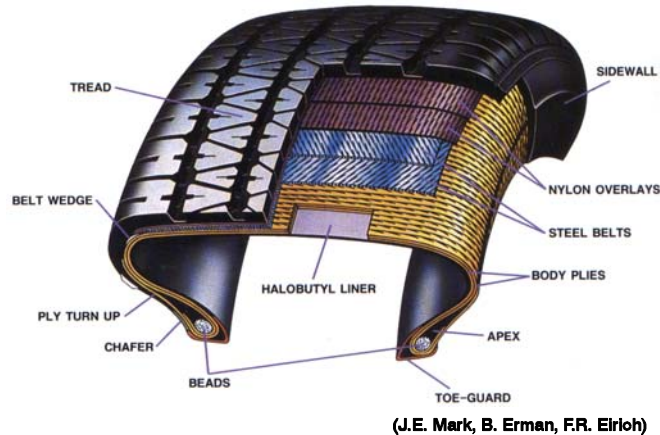


## Intention:

- Rules for substances in articles are to be applicable to millions of articles on the market.
- Under concern: Substances with a harmful potential to human health and environment
- REACH covers in "registration" all substances, released from the article during normal and reasonably foreseeable conditions of use.  
(substances present in articles  $\geq 1$  t/a)

# Components under concern

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Stable Materials  
like Polymer, Filler, Oils

From Supplier,  
Synthesis

Impurities

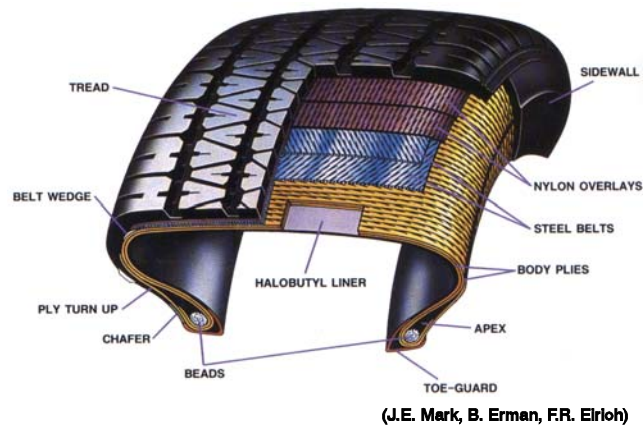
Unstable Materials

Antioxidants  
Accelerators  
Coupling Agents

From  
Processing,  
Use

Reaction Products  
in rubber material

# Tire compound materials



- composite material
- different rubber mixtures
- reinforcing materials
- processing

Component	Impurities	Toxic evaluation <sup>2)</sup>
Polymer <sup>1)</sup>	volatile Monomers, oligomers	(+)
Carbon Black	adsorbed PAH`s	+
Silica	-	-
Antioxidants	amines, oxidation products	+
Mineral oil	PAH`s (except. TDAE, MES)	+
Resins	phenol, formaldehyde	+
Processing aids	undefined	?
Waxes	none	-
Adhesives	phenol, formaldehyde	+
Silanes	none	-
Stearic acid	other fatty acids	-
Zinc oxide	heavy metals (Pb, Cu, Mn)	-
Accelerators	amines, sulfur components, degradation products,	+
Retarders	-	+
Sulfur	-	-

<sup>1)</sup>not relevant for REACH, if molecular weight fraction below 1000 Dalton < 2 %

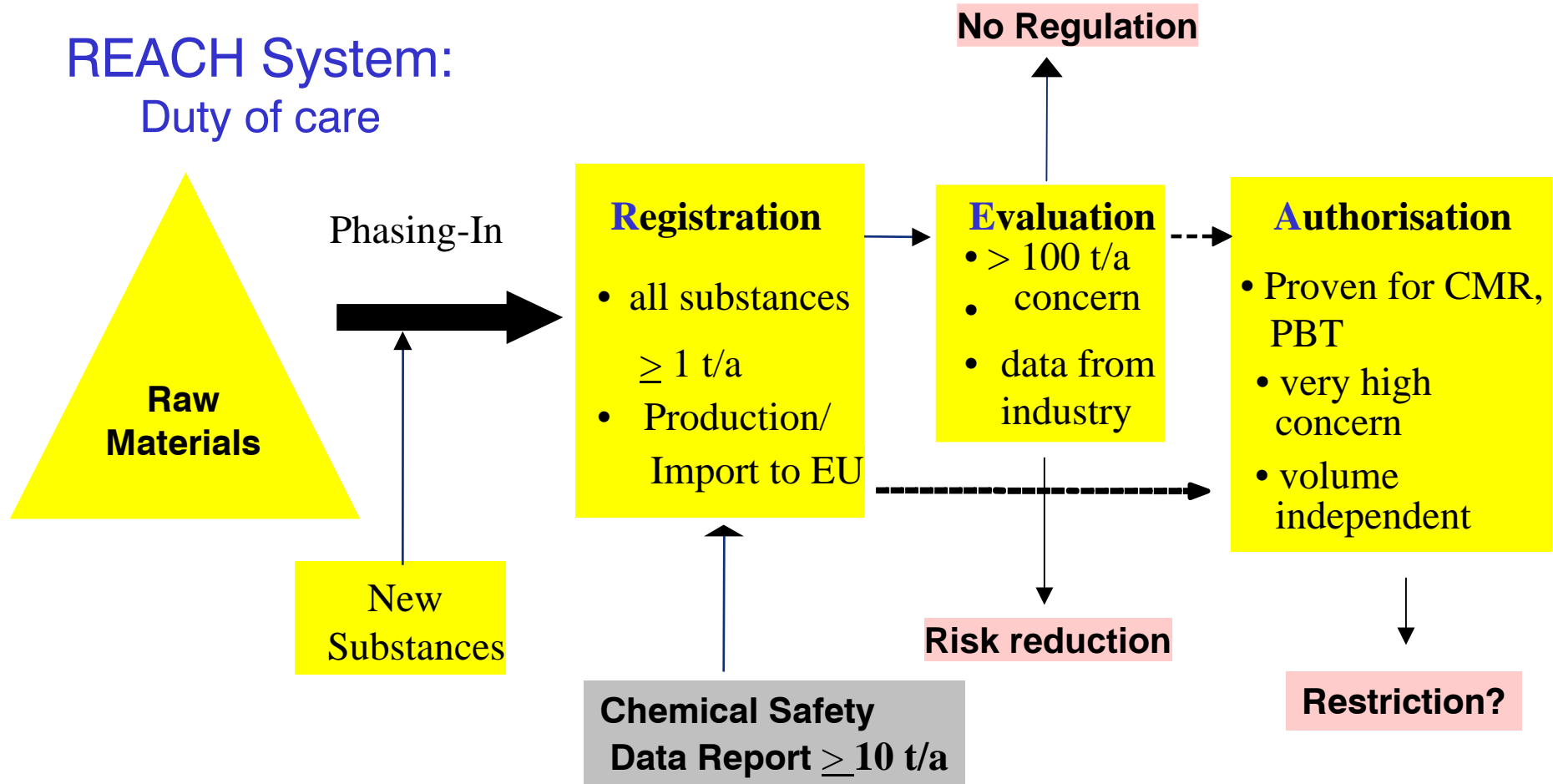
<sup>2)</sup>classified and labelling, (TLV, irritant, ecotoxicity etc.)

(+) classification as hazard depends on impurity type and content,  
 + classified  
 - non classified

# EU-Chemical Policy

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## REACH System: Duty of care



Source: Innovation Information Services  
Bayer Polymers 2003

CMR: carcinogenic, mutagenic, toxic to reproduction  
PBT : persistent, bioaccumulation, toxicity

# Requirements for Registration

**Chemical Safety Report (CSR)**  
**Data from suppliers**



**Extended**  
**Chemical Safety Report (CSR)**  
*Data for reaction products*  
*In rubber materials are required*

PT

## Manufacturer / Importer<sup>1)</sup>

- Information for safe management of chemicals
- Data on toxicity/ecotoxicity
- Definition of intended uses
- Evaluation of human and environmental exposure in intended uses (-> exposure categories)
- Preliminary risk assessment and recommended safety measures (exposure scenario)



## Downstream user

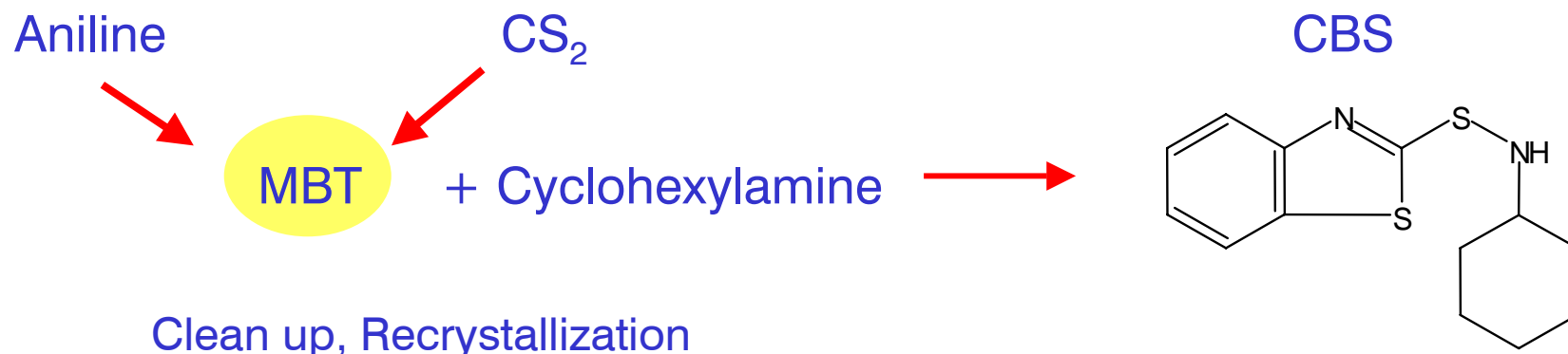
- Responsible for the safety of their products
- Check of intended use
- Check of exposure pattern in comparison to registered exposure categories
- Own registration requirements when uses and/or exposure patterns differ from those registered

<sup>1)</sup> Effect on industry, globally

# Impurities of Sulphenamides

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## Representative CBS:



Clean up, Recrystallization

CBS, pure

OEL 2,5 mg/m<sup>3</sup>  
R 51/53

### Impurities

- Aniline
- MBT
- CS<sub>2</sub>

OEL 2,5 mg/m<sup>3</sup>  
R50/53  
R 43

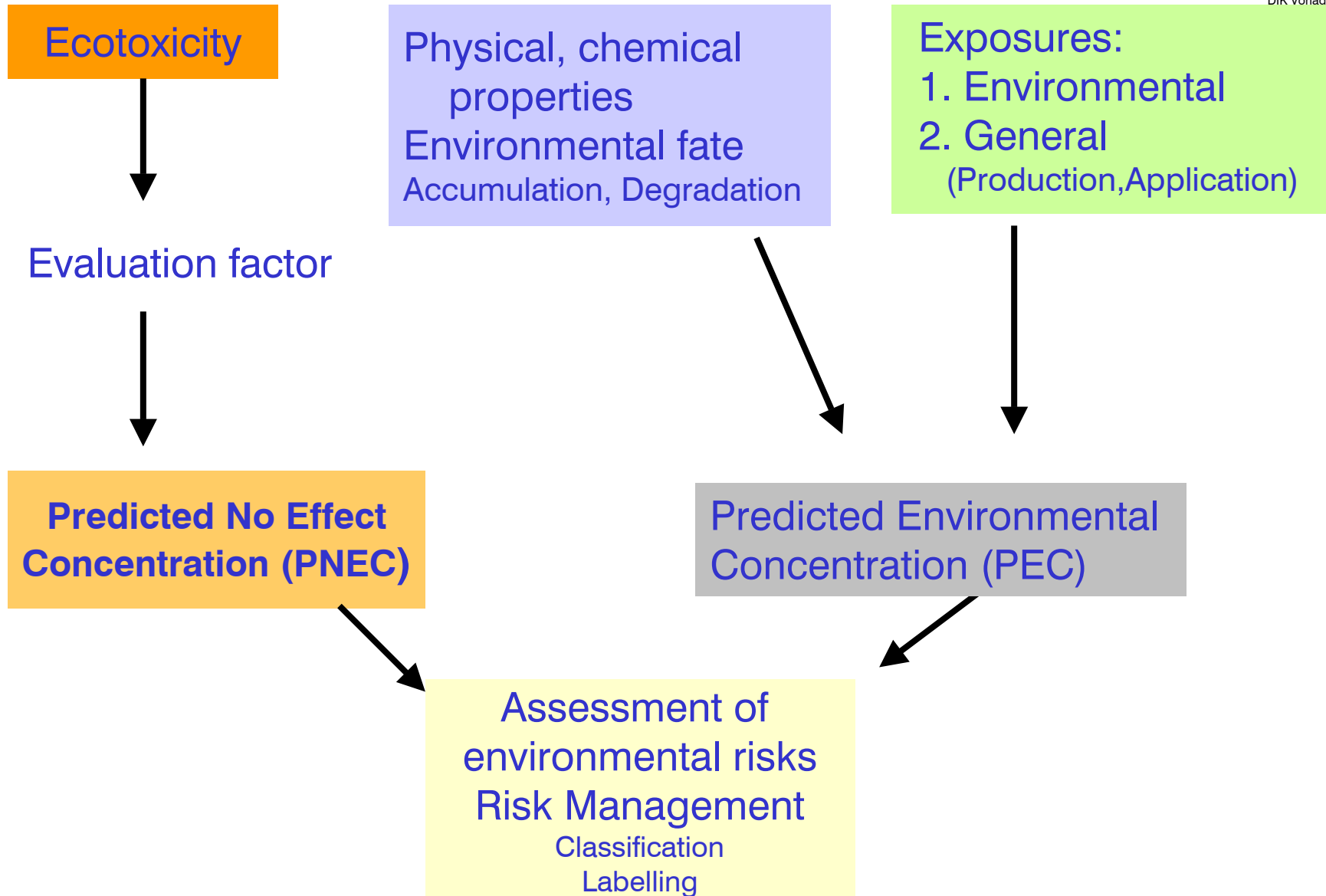
- High acute toxicity
- Cancerogene group 3
- No bioaccumulation
- Photodegradation
- OEL 7,7 mg/m<sup>3</sup>

Chemical Report  
Ministry of environment, Germany

Important factors for safety data report,  
available by supplier

# Risk Assessment for Chemicals

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# Impurities of IPPD and 6PPD

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## Risk Assessment of Aminodiphenylamine Ministry of Environment, Germany

### Environmental behaviour of 4-aminodiphenylamine

- low biological degradation in aquatic system (Laboratory tests)
- low biological degradation in soil (Half-life 227 days)
- Photooxidative degradation (Half-life 2 h)



$$\text{PEC/PNEC} = (11.4 / \mu\text{g/l}) / (<0.2 \mu\text{g/l})$$

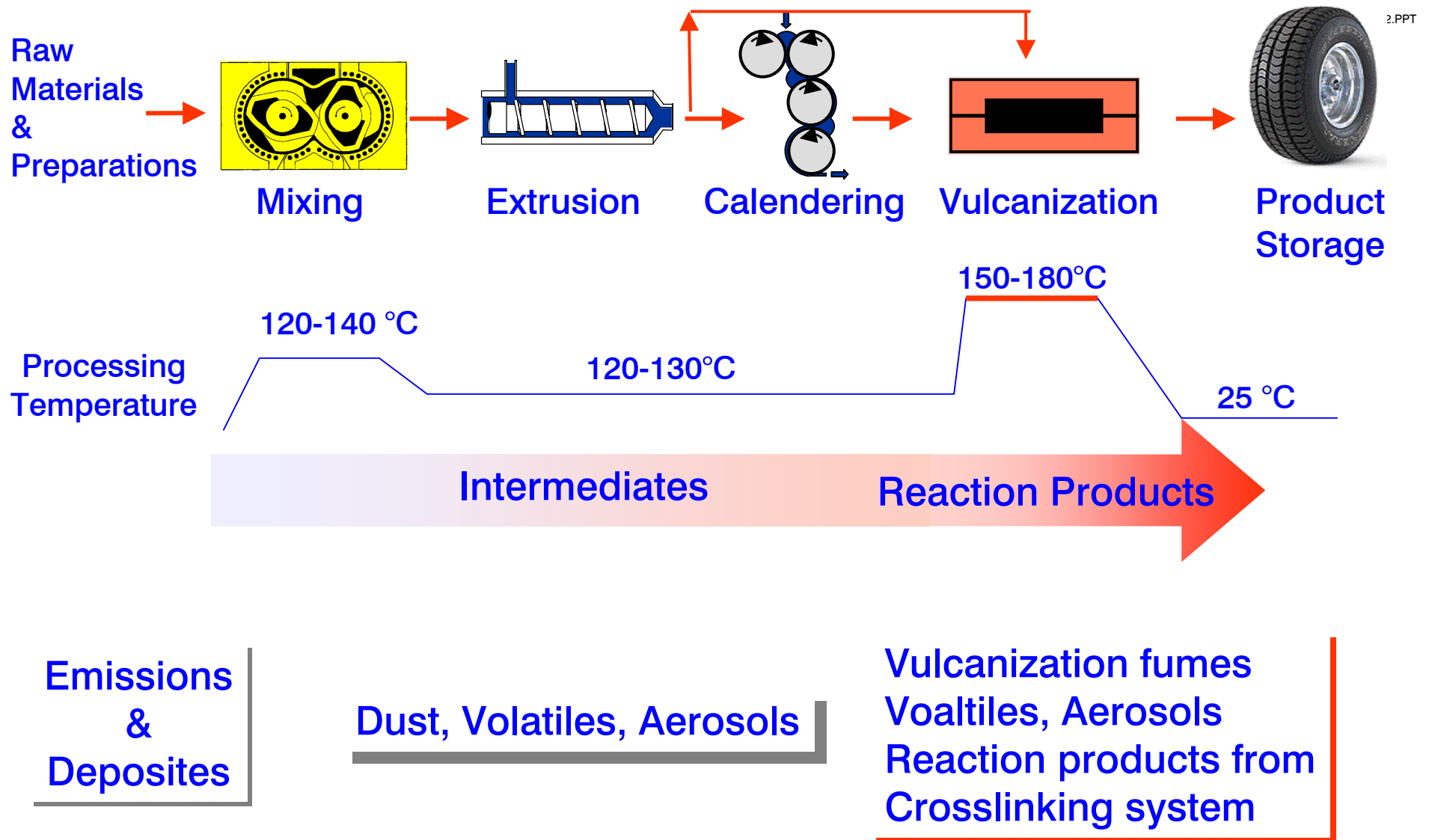
$$\text{PEC/PNEC} = >57$$

**Hazardous properties for environment**

**Comment: Data calculated, only few measurements**

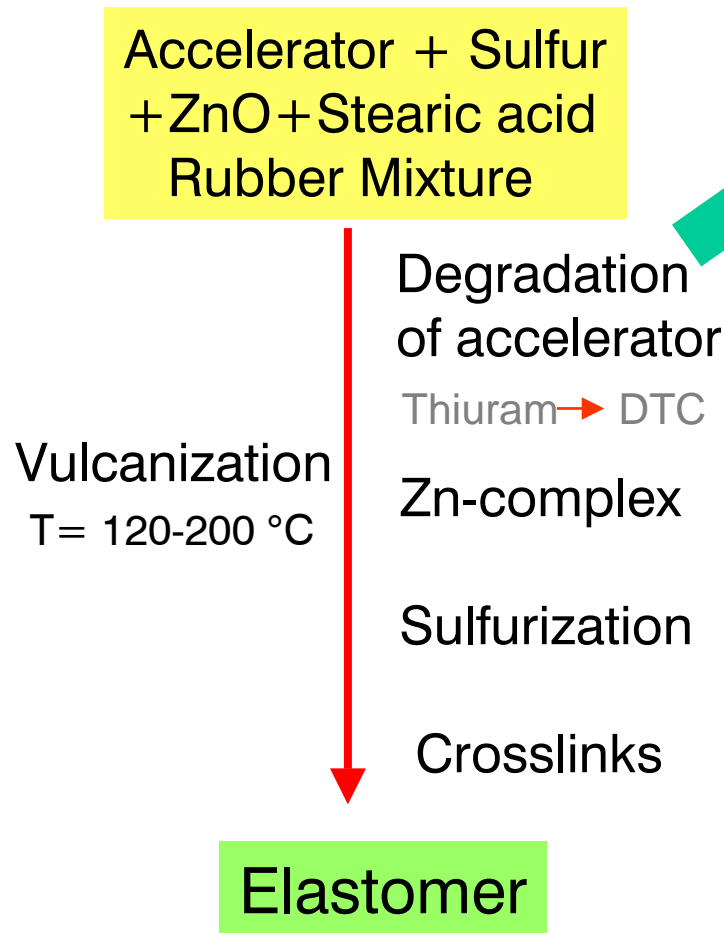
PEC: predicted environmental concentrations  
NOEC: No effect concentration

# Processing of Rubber Articles



# Accelerators-Overview

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Properties:

- Unstable components
- Decomposition:  $T > 120\text{ °C}$
- Formation of volatile, low molecular reaction products  
Thiurams/dithiocarbamates reduced, because Nitrosamines

	<b>Consumption<sup>1)</sup> t/a in tires</b> (WDK, German Rubber Ind.)
<b>CBS</b>	<b>1580.0</b>
<b>TBBS</b>	<b>700.0</b>
<b>MBTS</b>	<b>540.0</b>
<b>DPG</b>	<b>400-500</b>
<b>TMTD</b>	<b>48.0</b>
<b>MBT</b>	<b>22.0</b>
<b>TBzTD</b>	<b>4.4</b>
<b>ZDMC</b>	<b>0.9</b>
<b>ZDEC</b>	<b>2,7</b>

DTC: Dialkyldithiocarbamate

# Main Reaction Products of Accelerators in Tires

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## Thiurams and DTC

Alkylamines (p)  
Alkyl-arylmines (p)  
Carbondisulfide (p)  
Alkylamides (s)  
Alkylthioureas (s)  
Alkylureas (s)  
Carbonoxisulfide (s)  
Alkylisothiocyanates (s)

## Sulphenamides/ Benzthiazols

Benzthiazol (p)  
Methylbenzthiazol (s)  
MBT (p)  
Benzthiazolone (s)  
Cyclohexylamine (p)  
Cyclohexylisothiocyanate (s)  
Cyclohexanone (s)  
Tert. Butylamine (p)  
Tert. Butylisothiocyanate (s)  
Morpholine (p)  
Methylmorpholine (s)

## DPG/ODPG

Aniline (p)  
Diphenylthiourea (c)  
Phenylisothiocyanate (c)  
Phenylguanidine (p)  
Diphenylurea (c)  
o- toluidine

- Alkyl-substituents are corresponding to the accelerator structure
- Quantities are depending on S/Accelerator/ZnO- ratio and vulcanisation parameters

Abbreviations:

DTC: Dithiocarbamates

(p) : primary reaction products

(s) : secondary reaction products

(c) : in combination with thiurams/DTC`s

# Exposure of Accelerators/Reaction Products at road sides

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Field studies by Ministry of Environment, Germany 1998: Soil analyses  
W. Baumann, M. Ismeier

Methods:  
-Methylene chloride  
Extraction.  
-Sample clean up  
-GC-NPD or GC-MS

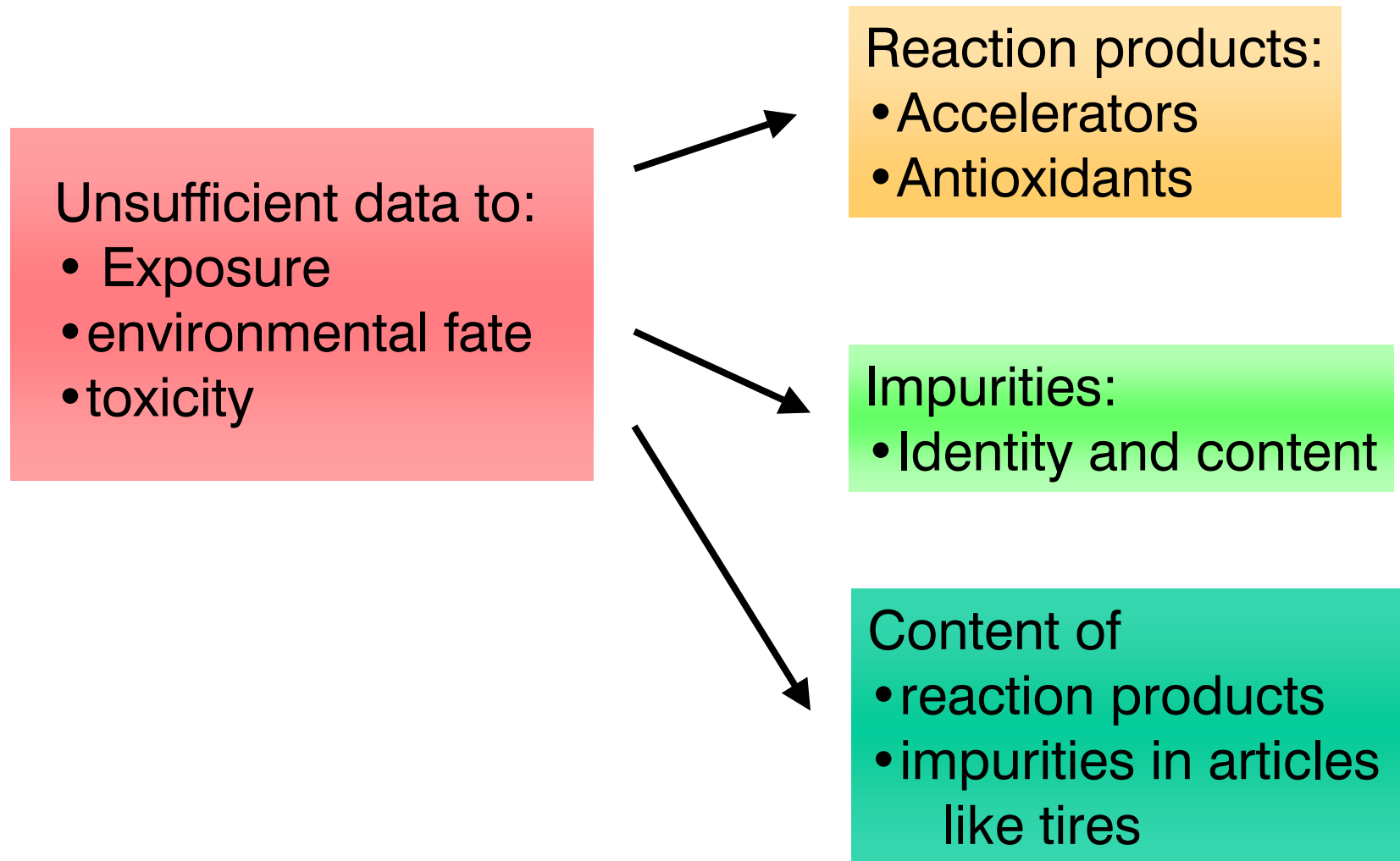
Sample	Benz-thiazole [mg/kg DS]	Methyl-benz-thiazole [mg/kg DS]	Methyl-mercapto-benz-thiazole [mg/kg DS]	Aniline [mg/kg DS]	Dicyclo-hexylamine [mg/kg DS]
10/0	17,4	4,63	9,15	<0,1	4,14
10/5	n.d.	n.d.	n.d.	n.d.	n.d.
10/10	n.d.	n.d.	n.d.	n.d.	n.d.
11/0	0,87	<0,5	1,00	n.d.	3,98
17/0	0,5	<0,5	2,27	n.d.	<3,00

With increasing distance from road, concentration decreases

DS – Dry Substance  
n.d. – not detected  
sample no /distance to road

Sample no 10: Highway region Dortmund, without industrial influences  
Sample no 11 and 17: Roads in a city

# Actual Situation of Data for CSR



# Availability of Chemicals ↔ REACH

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Estimated decrease in availability of chemicals:

- EU-Commission : 8-12 % of all chemicals
- VCI: 30-40% of chemicals  $\leq 100$  t/a
- EU-Commission in 2006: 1-2 % of all chemicals
- Special consequence in rubber industry:  
Change of recipes, new tests for  
specification conformity

# EU-Chemical Policy – Actual State

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- Classification and labels for rubber mixtures:

Mixtures containing hazards

Mixtures with a content > 0.25 % ZnO

Exception: No label, if there is shown that the compound causes no risk for environment. Scientific investigations for single products necessary. (WDK/BLIC has carried out this for some Technical Rubber Goods)

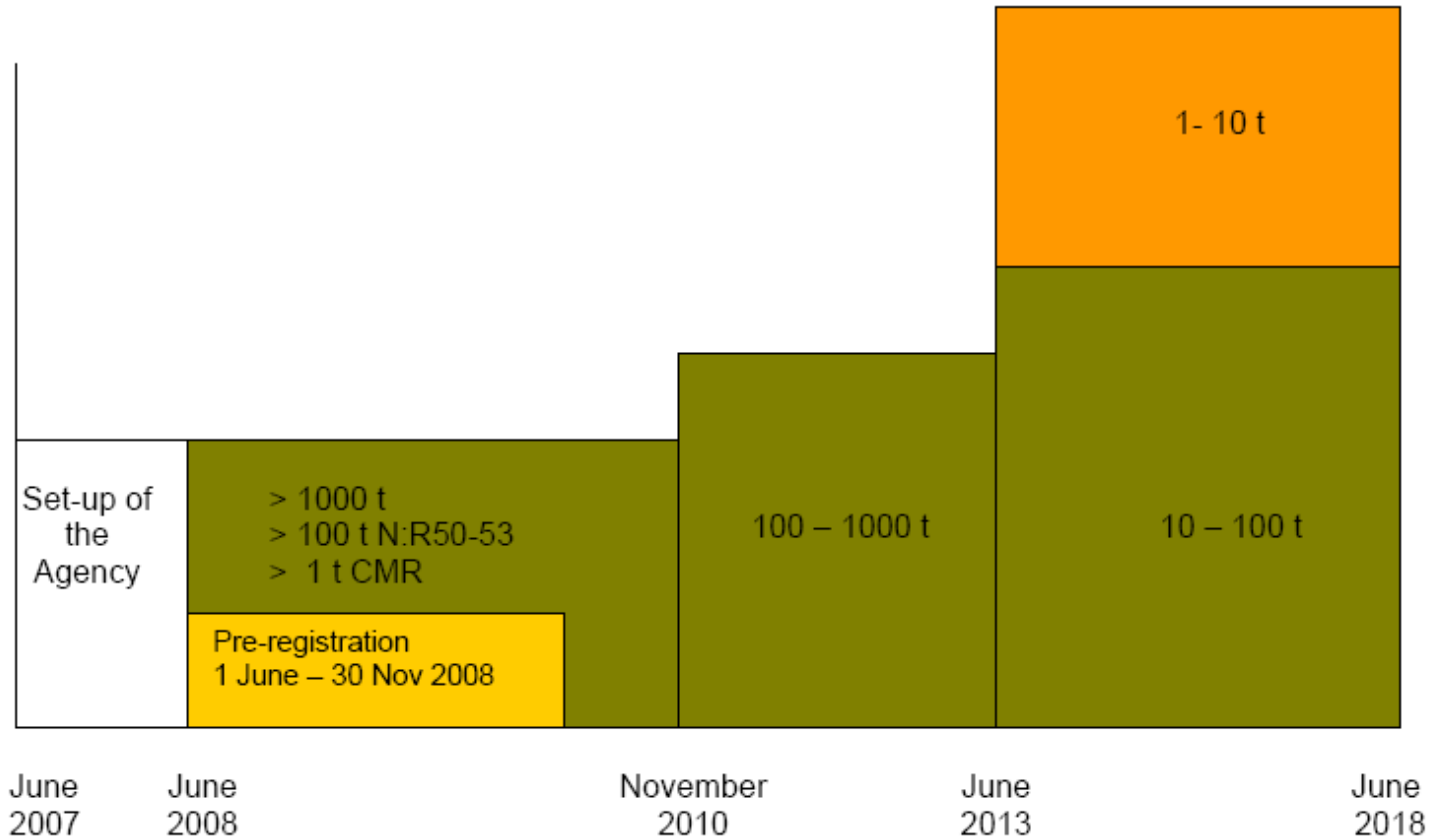
June/1/2007: REACH-legislation will be in operation  
Starting first steps for registrations of chemicals  
(Administration located in Helsinki)

Source:

Rubber Manufacturer Association (WDK), May 2006

# Registration: Time Scale for Deadlines

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# Summary - Costs and Benefits

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## Positive:

- Increase information on hazards and control
- Better implementation of existing legislation
- Positive impact on occupational and public health and on environment (exp. : 0,1-10 % reduction in diseases and deaths due to cancer of about 4,500)
- Replacement of 40 existing pieces of legislation → single system for all chemicals

## Negative:

Costs for chemicals industry:  
EUR 2.3 billion over first 11 years

Costs for Downstream users:  
EUR 0.5-1.3 billion<sup>1)</sup>  
(scenario: EUR 1.7-2.9 billion<sup>1)</sup>)

Registration costs : ~EUR 100,000  
/substance (production: 1-10 t/a)



Strategy: Bundle of chemicals from small suppliers to reduce registration costs

<sup>1)</sup> In German: "Milliarden"

Thank you